

European Respiratory Society Annual Congress 2013

Abstract Number: 7236

Publication Number: 2004

Abstract Group: 1.6. General Practice and Primary Care

Keyword 1: COPD - management **Keyword 2:** Primary care **Keyword 3:** Education

Title: A cluster randomised controlled trial evaluating the effectiveness of a structured pulmonary rehabilitation education programme in a primary care setting for people with chronic obstructive pulmonary disease (COPD): The PRINCE study

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Body: Little is known about the impact of structured education pulmonary rehabilitation programmes (SEPRP's) delivered in primary care. Objective: To evaluate the effectiveness of a SEPRP based in primary care, on the health status of people with COPD. Design: A two-arm, cluster RCT, with randomization at practice level. 32 primary care centers in Ireland. 178 participants with COPD were randomized to the intervention and 172 to control. Experimental group received SEPRP, delivered by a practice nurse and a physiotherapist, 2 hours per week over 8 weeks. Control group received usual care. Health status, measured by the CRQ at baseline and at 12-14 weeks was the primary outcome measure. Outcomes assessments were blinded to group allocation. 143 of 178 (52%) patients in the intervention and 134 of 172 (48%) in control completed post intervention assessments. Participants allocated to the intervention had statistically significant higher mean change total CRQ scores (adjusted mean difference (MD) 1.11, 95% CI 0.35 to 1.87). They also had statistically significant higher mean CRQ Dyspnoea scores after intervention (adjusted MD 0.49, 95% CI 0.20 to 0.78) and CRQ Physical scores (adjusted MD 0.37, 95% CI 0.14 to 0.60). However, CI's for total CRQ score, CRQ Dyspnoea and CRQ Physical subscales do not exclude smaller differences pre-specified as clinically important. The NNT for the Total CRQ was 7. No other statistically significant differences were seen. A SEPRP based in primary care is feasible and may increase local accessibility to people with COPD.